

**REMARKS**

This response addresses the issues raised by the Examiner in the Office Action mailed August 10, 2004. Initially, Applicant would like to thank the Examiner for the careful consideration given in this case. Claims 7 and 14 have been currently amended and Claims 3 and 9 have been canceled. New Claims 15-18 have been added. Accordingly, Claims 4-8 and 10-18 are pending in this case all to more clearly and distinctly claim Applicant's invention. Applicant respectfully requests entry of the amendments as they place the application in condition for allowance or in better condition for possible appeal.

Claim 7 has been amended to add that the mesh layer has an aperture diameter of 0.05 to 7.5 mm and defines compartments on the surface of the water impermeable support, the compartments have a hydrophilic bottom surface, wherein said hydrophilic bottom surface is coated with a transparent, water soluble, swelling, hydrophilic polymer having a thickness of 2 to 100  $\mu\text{m}$  in dry state, and an open top surface,; and all reagents necessary for analysis in the compartments. Support for this amendment appears for example, in the specification at page 8, lines 7-19, 23-24; page 9, line 26; page 11, lines 1-5, 7-13, 15, 17; page 12, lines 26-27; and page 15, line 12. Further, the limitation of Claim 9 has been incorporated into Claim 7.

Claim 14 has been amended to add that the hydrophilic bottom surface is coated with a transparent, water soluble, swelling, hydrophilic polymer having a thickness of 2 to 100  $\mu\text{m}$  in dry state, and an open top surface, and all reagents necessary for analysis in the compartments. Support for this amendment appears for example, in the specification at page 8, lines 7-19, 23-24; page 9, line 26; page 11, lines 1-5, 7-13, 15, 17; page 12, lines 26-27; and page 15, line 12. Further, the limitation of Claim 3 has been incorporated into Claim 14.

Additionally, Applicant has added new Claims 15 and 17 in which the polymer is a member selected from the group consisting of polyvinyl alcohol, polyacrylamide, polyvinyl pyrrolidine, polymethyl vinyl ether, copolymer of polyacrylamide and polyvinyl pyrrolidone, methyl cellulose derivative, crosslinked starch-acrylate graft copolymer, crosslinked polyacrylic acid, gelatin, gelatin derivative and carboxymethyl starch, support for these new claims may for example be found on page 8, lines 11-19 and page 11, lines 6-14 of the specification, respectively.

Further, Applicant has added new Claims 16 and 18 in which the water impermeable support is transparent film of from 50  $\mu\text{m}$  to 1 mm in thickness made of a member selected from the group consisting of polyethylene terephthalate, polycarbonate of biphenol A, polystyrene and cellulose ester, support for these new claims may for example be found on page 7, lines 12-18 and pages 11-12, lines 22 to line 1 of page 12 of the specification, respectively. Accordingly, it is respectfully submitted that no new matter has been added by the amendments.

**Rejection Based On Kearns Under 35 U.S.C. § 102 (b)**

The Examiner rejects Claims 3, 6-10 and 13-14 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent 5,573,919 to Kearns et al. as applied to currently amended Claims 7 and 14 and new Claims 15-18. Applicant respectfully traverses this rejection.

The Examiner asserts that Kearns teach a device having a support in the form of a microtiter plate comprising an absorbent substrate in surface where there are a plurality of well bound by circular walls, where each well includes a surface that accepts the sample and reagent. The Examiner states that Kearns discloses that the absorbent substrate is hydrophilic

and being made a mesh to which reagents is attached. Thus, the Examiner concludes that the present invention is anticipated by Kearns. Applicant respectfully disagrees.

To establish obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP § 2143.03. Kearns does not disclose a dry analytical element but a microtiter plate, which may be directed to tray 60. See Col. 4, lines 9-17. In addition, Kearns does not disclose a mesh layer having a aperture diameter of 0.05 to 7.5 mm with compartments on the surface where each compartment has a hydrophilic bottom, wherein said hydrophilic bottom surface is coated with a transparent, water soluble, swelling, hydrophilic polymer having a thickness of 2 to 100  $\mu\text{m}$  in dry state, and an open top surface, and all reagents necessary for analysis in the compartments. Kearns instead discloses a thick absorbent substrate that is merely placed in tray 60. The absorbent substrate is made of polyolefin, polyester, polyvinyl chloride, polystyrene which are hydrophobic and water-insoluble. See Col. 6, lines 4-6. Further, since the absorbent substrate is porous they should be opaque. See Col. 6, line 8. Moreover, the thickness of absorbent substrate is much thicker than the hydrophilic polymer layer of the invention as shown in Figure 6 and in the Example where pore size of 30 microns is indicated.

In contrast, the present invention claims a dry analytical element including a water impermeable support, a mesh layer where the mesh layer has an aperture diameter of 0.05 to 7.5 mm and defines compartments on the surface of the water impermeable support. The compartments of the present invention include a hydrophilic bottom surface where the hydrophilic bottom surface is coated with a transparent, water soluble, swelling, hydrophilic polymer having a thickness of 2 to 100  $\mu\text{m}$  in dry state, and an open top surface and all reagents necessary for analysis in the compartments. The present invention also claims a dry analytical element that includes a water impermeable support, a water impermeable frame

body which defines a compartment on the water impermeable support. The compartment of the present invention has a hydrophilic bottom surface, wherein said hydrophilic bottom surface is coated with a transparent, water soluble, swelling, hydrophilic polymer having a thickness of 2 to 100  $\mu\text{m}$  in dry state, and an open top surface and all reagents necessary for analysis in the compartment.

The purpose of the support of the dry analytical element of the present invention prevents the permeation of liquid sample to assist in the planar dispersion of the sample. This is achieved in the present invention by the thin layer of coating of the specified polymer on the water impermeable support. In contrast, the tray of Kearns is a mere container (col. 4, lines 15-16). In order to induce a similar phenomenon in Kearns, a great volume of samples must be supplied which makes analysis impossible by mixing samples supplied to adjacent or farther wells. Moreover, function of the water impermeable support of the present invention is different from the tray of Kearns. Specifically, the support of the dry analytical element of the present invention prevents the permeation of liquid sample to assist in the planar dispersion of the sample.

The present invention also claims having a hydrophilic polymer layer that forms the hydrophilic bottom surface is water-soluble, swelling, transparent and very thin, i.e. 2  $\mu\text{m}$  to 100  $\mu\text{m}$  in thickness in the dry state. In contrast, the absorbent substrate of Kearns is made of polyolefin, polyester, polyvinyl chloride, polystyrene which are hydrophobic and water-insoluble. See Col. 6, lines 4-6. Further, since the absorbent substrate is porous they should be opaque. See Col. 6, line 8. Moreover, the thickness of absorbent substrate is much thicker than the hydrophilic polymer layer of the invention as shown in Figure 6. The example in Col. 10, line 36 of Kearns discloses that the pore size of the porous plastic support is 30

microns. In any event, Kearns does not teach the use of a hydrophilic polymer, as currently claimed in independent Claims 7 and 14.

Moreover, the function of the hydrophilic polymer layer of the present invention is also different from the absorbent substrate of Kearns. The hydrophilic polymer layer spreads a liquid sample in a planar direction uniformly. On the other hand, the absorbent substrate of Kearns passes a liquid sample through capillaries formed by its porous structure to catch analyte by the binder supported in the absorbent substrate (col. 1, lines 41-51). That is, in the absorbent substrate, a liquid sample flows vertically – not in a planar direction.

The currently claimed mesh layer of the present invention has an aperture diameter of 0.05 to 7.5 mm and defines compartments on the surface of the water impermeable support. The Examiner asserts in the previous Office Action, that the absorbent substrate as being made of mesh in Kearns. However, the absorbent substrate described in Kearns has a porosity capable of retaining non-charged particles of at least 0.1 micron and no greater than 10 microns (Col. 5, lines 28-31), which are smaller pore sizes than the above particle size. Accordingly, the aperture diameter of the mesh of the present invention is quite different from the absorbent substrate of Kearns. Kearns does not disclose the mesh layer of the present invention.

The device of Kearns is used for ELISA assay, where antigen-antibody reaction is first allowed to occur, followed by measuring enzyme activity. See Col. 5, line 1. The reagents incorporated in Kearns device are for the antigen-antibody reaction and detecting reagents are added after the antigen-antibody reaction. See Col. 3, lines 10-16 and Col. 10-11 lines 65-11. Thus, the device of Kearns does not contain all reagents necessary for analysis, and it is necessary to have two steps (1) to add a sample, and (2) to add reagents for detection

after that. Moreover the analytical results are + or - , qualitative by one well (Fig. 1), and semi-quantitative by a series of wells (Fig. 5).

In contrast, the present invention discloses a dry analytical element that is characterized by containing all reagents necessary for analysis, uniform spreading in the planar direction and one step analysis. Uniform spreading in the present invention is achieved by a combination of thin layer of hydrophilic polymer and a water impermeable support which forces the sample to spread in a planar direction. Moreover, the analytical results are quantitative. Accordingly, Kearns does not disclose an analytical element that is characterized by containing all reagents necessary for analysis, uniform spreading in the planar direction and one step analysis. Thus, Kearns does not disclose each and every claim element of the claimed invention. Accordingly, Applicant respectfully requests that the rejection under 35 U.S.C. § 102 (b) be reconsidered and withdrawn.

**Rejection Based On Kearns Under 35 U.S.C. § 103 (a)**

The Examiner rejects Claims 4-5 and 11-12 under 35 U.S.C. § 103(a) as being unpatentable over by U.S. Patent 5,573,919 to Kearns et al. as applied to currently amended Claims 7 and 14 and new Claims 15-18. Applicant respectfully traverses this rejection.

Although the Examiner acknowledges that Kearns is silent to the claimed tetragon and hexagon shapes, the Examiner concludes that it would have been within the skill of the art to modify Kearns and use a tetragon or hexagon shape for the plate to minimize the void volume between interconnecting plated because the configuration of the plate is a matter of choice.

Applicant respectfully disagrees with the Examiner. To establish obviousness of a claimed invention, all claim elements must be disclosed, taught or suggested by the prior art. It is submitted that the arguments presented *supra* regarding Kearns are applicable in

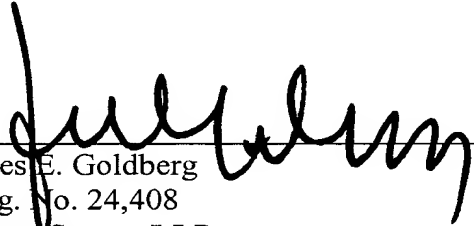
addressing the present obviousness rejection. It is respectfully submitted that as presently pending, the claims are allowable over the cited art. Reconsideration and withdrawal of the pending obviousness rejection is respectfully requested.

In view of the remarks presented herein, it is respectfully submitted that the present application is in condition for final allowance and notice to such effect is requested. If the Examiner believes that additional issues need to be resolved before this application can be passed to issue, the undersigned invites the Examiner to contact him at the telephone number provided below.

Respectfully submitted,

Dated: December 10, 2004

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